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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/560,024	02/20/96	CHEN Y	LUD-5354.1-J

18N2/0113

FELFE AND LYNCH
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EXAMINER	
CAPUTA,A	
ART UNIT	**PAPER NUMBER**
1817	//

DATE MAILED: 01/13/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
08/560,024	Chen et al.
Examiner	**Group Art Unit**
Anthony C. Caputa	1817

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☐ expires _____ months from the mailing date of the final rejection.

b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *15 Dec 1997* **has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☒ The proposed amendment(s):

☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

☐ they raise new issues that would require further consideration and/or search. (See note below).

☐ they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s):

_____

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attachment

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: *11, 12, 15, and 16*

Claims objected to: *17*

Claims rejected: *8-10, 13, and 14*

☐ The proposed drawing correction filed on _____ ☐has ☐has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☐ Other

ANTHONY C. CAPUTA
PRIMARY EXAMINER
ART UNIT 1817

ADVISORY ACTION

1. The prior objection to the specification under 35 U.S.C. § 112, first paragraph for failing to provide an enabling disclosure is maintained for the reasons as set forth of record.

Applicants argue the rejection should be withdrawn since the references cited by the Examiner (e.g. Lazar et al., and Burgess et al.) are drawn to a non-analogous area (i.e. growth factors) and not a tumor rejection antigen precursor. Applicants arguments are not persuasive to obviate the rejection. The Examiner acknowledges the that the prior art cited is drawn to 2 proteins which are growth factors. However, since:

1.) both the claimed invention and art cited are drawn to proteins; and

2.) the art cited (e.g. Lazar et al., and Burgess et al.) teaches modifications of two proteins with different structure and function dramatically affect the biological activity of these proteins

it is reasonable for a skilled artisan to conclude the biological activity of a protein, such as the MAGE-1 will be dramatically affected contrary to applicants arguments.

Applicants argue the rejection should be withdrawn in view of the decision of *Ex parte Anderson* 30 USPQ 2d 1866, 1868 (Bd. Pat. App. Int. 1994), wherein it was determined that as a normal rule, single amino acid changes in amino acid sequence do not affect the activity of a protein.

Applicants arguments are not persuasive. From the decision of *Ex parte Anderson* it is clear that a single variation in the amino acid structure of the protein will change the activity and functions of the protein, when said variation is in a critical region of the protein (see page 1868, Column 1 of the decision of *Ex parte Anderson* as cited by Applicants). Since the specification fails to provide guidance of what regions of protein are associated with the activity and functions of the protein, and lack of predictability associated with regard to producing and using the myriad or derivatives encompassed in the scope of the claims one skilled in the art one would be forced

into undue experimentation in order to practice broadly the claimed invention, contrary to applicants arguments.

Applicants further argue the allowed claims in U.S. Patent No. 5,342,774 support the enablement of the claims of the instant application. Applicants arguments are not persuasive since the scope of claims in the issued patent are not as broad as the claims of the instant application. The claimed nucleic acid of issued patent 5,342,774 is drawn only to those nucleic acid molecules which encode for a tumor rejection antigen precursor and hybridize under stringent conditions to the nucleic acid molecule as recited. In contrast the claimed invention is not drawn to a particular tumor rejection antigen precursor, wherein the nucleic acid that encodes for said antigen hybridizes under stringent conditions to a nucleic acid with a defined sequence. The claims of the instant application in a broad interpretation encompass a particular tumor rejection antigen precursor, wherein the nucleic acid which encodes for said antigen precursor hybridize under any conditions to a nucleic acid with no defined sequence. The scope of the claims must bear a reasonable correlation with the scope of enablement. See in re Fischer, 166 USPQ 19 24 (CCPA 1970).

In response to applicants argument that the claimed invention is enabled since a tumor rejection antigen precursor is processed to a TRA of 8-12 amino acids which is presented on a cell surface in combination with a MHC molecule (see pages 2-6 of the specification). This argument is not sufficient to obviate the rejection since: 1) the limitation that the tumor rejection antigen precursor is processed to a TRA of 8-12 amino acids which is presented on a cell surface in combination with a MHC molecule is not recited in the rejected claim(s) and; 2) pages 2-6 of the specification do not set forth tumor rejection antigen precursor are processed to a TRA of 8-12 amino acids which is presented on a cell surface in combination with a MHC molecule. Beyond this applicants arguments are not persuasive to obviate the rejection because: 1) the specification provide essentially no guidance as to which of the essentially infinite possible choices

of peptides is likely to be successful and; 2) the art cited (e.g. Lazar et al., and Burgess et al.) teaches modifications affect biological activity.

As set forth previously the Examiner suggest applicants incorporate the limitation of claim 17 into claim 8 to obviate the rejection.

2. Claims 8-10, 13, and 14 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

3. The prior rejection of claims 17 and 20 under 35 U.S.C. 112, second paragraph for lack of antecedent basis for use of the phrase "claim 1" is withdrawn in view of applicants' amendment.

4. The prior rejection of claim 8 under 35 U.S.C. 112, second paragraph for being in an improper Markush format is withdrawn in view of applicants' amendment.

5. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth previously while the specification has support for claiming an peptide consisting of SEQ ID NOS 2, 3, or 4 (see allowed claim 12) the specification as originally filed provides no support for claiming a MAGE-1 tumor rejection comprising all of these sequences (claim 20).

Applicants assert that the rejection should be withdrawn in view of the statement that 'Based upon predicting MAGE-1 amino acid sequence, three oligopeptides were sequenced" (see Example 2. Applicants further argue the rejection should be withdrawn in view that multiple

codons correspond to one amino acid. Applicants arguments are not sufficient to obviate the rejection. While it is true the specification provides support of three oligopeptides prepared from the predicted amino acid sequence of MAGE-1 this statement does not provide support for broadly claiming a MAGE-1 comprising all of these sequences as recited. The specification as originally filed does not provide an adequate written description of a MAGE-1, wherein the location of the recited sequences are found at any position within the MAGE-1. Furthermore, the specification as originally filed does not provide written description for claiming a MAGE-1 tumor rejection antigen precursor limited to a sequence of 40 amino acids, particularly since the MAGE-1 tumor rejection antigen precursor of Example 1 as pointed out by applicants comprises more than 40 amino acids.

6. Claims 11, 12, 15, and 16 are allowed.

7. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. The examiner can be reached on alternate Fridays. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196.

Papers related to this application may be submitted to Art Unit 1817 by facsimile transmission. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The Fax number is (703)-308-4242.

Anthony C. Caputa, Ph.D.
January 12, 1998

ANTHONY C. CAPUTA
PRIMARY EXAMINER
GROUP 1800